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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,393	10/07/2003	Arthur G. Taveras	OC01643K1	5744

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SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER	
SOLOLA, TAOFIQ A	
ART UNIT	PAPER NUMBER
1626	

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/680,393	TAVERAS ET AL.	
	Examiner	Art Unit	
	Taofiq A. Solola	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-131 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1-131 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 1-131 are pending in this application.

DETAILED ACTION

Election/Restriction

1. The Markush group set forth in the claims includes both independent and distinct inventions, and patentably distinct compounds (or species) within each invention. However, this application discloses and claims a plurality of patentably distinct inventions far too numerous to list individually. Moreover, each of these inventions contains a plurality of patentably distinct compounds, also far too numerous to list individually. For these reasons provided below, restriction to one of the following Groups is required under 35 U.S.C. 121, wherein an Group is a set of patentably distinct inventions of a broad statutory category (e.g. Compounds, Methods of Use, Methods of Making, etc.):

I. Claims 1-73, drawn to compounds of formula (I) and composition thereof, classified in several heterocyclic classes (540, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

II. Claim 74, 83-84, 100, 109-110, drawn to methods of treating chemokine-mediated diseases, classified in classes 514, 540, 544, 548, 560, various subclasses.

III. Claim 75-79, 101-105, drawn to methods of treating cancer, classified in classes 424, 514, 548, 560, various subclasses.

IV. Claim 80-82, 106-108, drawn to methods of inhibiting or treating angiogenesis, classified in classes 434, 514, 548, 560, various subclasses.

V. Claims 82, 108, 126-127, drawn to method of treating numerous diseases, classified in several heterocyclic classes (514, 549, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VI. Claim 82, 85, 108, 111, drawn to methods of treating pulmonary diseases, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VII. Claim 86-87, 112-113, drawn to methods of treating multiple sclerosis, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

VIII. Claim 82, 88-89, 98-99, 108, 114-115, 124-125, drawn to methods of treating rheumatoid arthritis, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

IX. Claim 90-91, 108, 116-117, drawn to methods of treating stroke and cardiac reperfusion injury, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

X. Claim 82, 92, 108, 118, drawn to methods of treating psoriasis, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XI. Claim 82, 93, 108, 119, drawn to methods of treating COPD, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XII. Claim 82, 94, 108, 120, drawn to methods of treating acute pain, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XIII. Claim 82, 95-96, 108, 121-122, drawn to methods of treating inflammatory diseases, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XIV. Claim 82, 97, 108, 123, drawn to methods of treating neuropathic pain, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XV. Claim 128, 130, drawn to methods of treating CXCR1 and/or CXCR2 mediated diseases, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

XVI. Claim 129, 131, drawn to methods of treating CXCR7 mediated diseases, classified in several heterocyclic classes (514, 558, 544, 544, 548, 546) and non-heterocyclic classes (558, 562, etc.), numerous subclasses.

2. In addition to an election of one of the inventions of group I-XVI above, restriction is further required under 35 U.S.C. 121 as follows:

3. If any of groups II-XVI is elected, applicant must elect a specific disease(s), which have support in the specification via testing or journal articles.

In accordance with the decisions in ***In re Harnisch***, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and ***Ex parte Hozumi***, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 U.S.C. 103.

4. If any election of Groups I-XVI is made, an election of a single compound (or set of compounds) is further required including an exact definition of each substitution on the base molecule (Formula IA), wherein a single member at each substituent group or moiety is selected. For example, if a base molecule has a substituent group R1, wherein R1 is recited to be any one of H, OH, COOH, aryl, alkoxy, halogen, amino, etc., then applicant must select a single substituent of R1, for example OH or aryl, and each subsequent variable position.

In the instant case, Applicant must elect one representative for each of A, B, g, in formula (IA), and the point of attachment of each elected substituent must be specified. The elected substituents must be specific not generic. Applicant must provide the structure of the elected compound.

Upon election of a single compound (or set of compounds), the Office will review the claims and disclosure to determine the scope of the independent invention encompassing the elected compound (compounds which are so similar thereto as to be within the same inventive concept and reduction to practice). The scope of an independent invention will encompass all compounds within the scope of the claim, which fall into the same class and subclass as the elected compound (or set of compounds), but may also include additional compounds, which fall in related subclasses. Examination will then proceed on the elected compound AND the entire scope of the invention encompassing the elected compound as defined by common classification. A clear statement of the examined invention, defined by those class(es) and subclass(es) will be set forth in the first action on the merits. Note that the restriction requirement will not be made final until such time as applicant is informed of the

full scope of compounds along with process of using said compound under examination. This will be set forth by reference to specific class(es) and subclass(es) examined. Should applicant traverse on the ground that the compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the compounds to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C 103(a) of the other.

All compounds falling outside the class(es) and subclass(es) of the selected compound and any other subclass encompassed by the election above will be directed to nonelected subject matter and will be withdrawn from consideration under 35 U.S.C. 121 and 37 C.F.R. 1.142(b). Applicant may reserve the right to file divisional applications on the remaining subject matter. The provisions of 35 U.S.C. 121 apply with regard to double patenting covering divisional applications.

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventors must be amended in compliance with 37C.F.R. 1.48(b) if one of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the fee required under 37CFR 1.17(i).
If desired upon election of a single compound, applicants can review the claims and disclosure to determine the scope of the invention and can **set forth** a group of compounds, which are so similar within the same inventive concept and reduction to practice. Markush claims must be provided with support in the disclosure for each member of the Markush group. See MPEP 608.01(p). Applicant should exercise caution in making a selection of a single member for each substituent group on the base molecule to be consistent with the written description.

Rationale Establishing Patentable Distinctiveness Within Each Group

Each Invention Set listed above is directed to or involves the use or making of compounds which are recognized in the art as being distinct from one another because of their diverse chemical structure, their different chemical properties, modes of action, different effects and reactive conditions (MPEP 806.04, MPEP 808.01). Additionally, the level of skill in the art is not such that one invention would be obvious over either of the other inventions, i.e. they are

patentable over each other. Chemical structures, which are similar are presumed to function similarly, whereas chemical structures that are not similar are not presumed to function similarly. The presumption even for similar chemical structures though is not irrebutable, but may be overcome by scientific reasoning or evidence showing that the structure of the prior art would not have been expected to function as the structure of the claimed invention. Note that in accordance with the holdings of Application of Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (CCPA 1963) and In re Lalu, 223 USPQ 1257 (Fed. Cir. 1984), chemical structures are patentably distinct where the structures are either not structurally similar, or the prior art fails to suggest a function of a claimed compound would have been expected from a similar structure.

The above Groups represent general areas wherein the inventions are independent and distinct, each from the other because of the following reasons:

The inventions of groups I and II-XVI are related as product and method of using respectively. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using the product (MPEP 806.05(h)). In the instant case, the product as claimed could be used in materially different utilities as demonstrated throughout the specification and in groups II-XVI, which are directed to different methods of using the product.

Each of the different methods of use of the invention set forth in Groups II-XVI is unrelated to others. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Methods of use are unrelated if one of three differences are found between them. These differences are 1) the population being treated, 2) the

material being used, and 3) the methodology for treatment. If any one or more of these differences exist and are patentably distinct, then the methods are unrelated. In the instant case, the different methods of use of the compounds are unrelated because the patient population treated for each disease is divergent.

In addition, because of the plethora of classes and subclasses in each of the Groups, a serious burden is imposed on the examiner to perform a complete search of the defined areas. Therefore, because of the reasons given above, the restriction set forth is proper and not to restrict would impose a serious burden in the examination of this application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

A telephone call was made to Henry Jeanette on 3/10/05 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taofiq A. Solola, PhD, JD, whose telephone number is (571) 272-0709.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Joseph McKane, can be reached on (571) 272-0699. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

TAOFIQ SOLOLA
PRIMARY EXAMINER
Group 1626

March 17, 2005